

# United States Senate

WASHINGTON, DC 20510

April 15, 1999

0501 '99 APR 26 A11:50

Jane E. Henney, Commissioner  
U. S. Food and Drug Administration  
5600 Fisher's Lane  
Rockville, MD 20857

Dear Commissioner Henney:

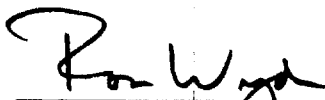
We are writing in response to the Food and Drug Administration (FDA) Request for Comments [Docket No. 98P-0504] on performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. We are concerned the Interstate Shellfish Sanitation Conference (ISSC), which normally plays an important role in establishing policies and regulations for shellfish safety, may have been circumvented. In addition, we question the advisability of basing public health policy on the last two anomalous hot (El Nino) summers, and we recommend any further action in response to the Request for Comments involve the ISSC.

Since 1982, the Interstate Shellfish Sanitation Conference has brought state and federal regulatory agencies, the shellfish industry and the academic community together to promote enhanced shellfish safety. Although the West Coast shellfish industry has experienced some frustration with the ISSC process in the past, especially with respect to the Gulf Coast's historical problems with *V. vulnificus*, it is our understanding the industry still believes the ISSC process is the democratic solution to many complex issues related to shellfish safety.

On the West Coast, where *V. parahaemolyticus* has been a problem, particularly for the past two uncommonly warm summers, the shellfish industry worked with their regulators through the ISSC process to develop a control plan. That plan, put into place this past summer, appears to have been highly effective in reducing illnesses caused by these bacteria. Since the plan also calls for data collection while simultaneously reducing illnesses, it would appear to be a logical course of action to continue using the plan through the next two summers to better assess the situation. These are the kinds of promising results we believe can be achieved when the industry and regulators work together to improve shellfish safety.

Thank you for your consideration of our comments in the process of developing performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. We look forward to working with the Food and Drug Administration to develop policies which promote the complementary goals of enhanced seafood safety and a growing shellfish industry.

Sincerely,



Ron Wyden  
U.S. Senate



Gordon H. Smith  
U.S. Senate

cc: Dockets Management Branch [Docket No. 98P-0504] ✓  
Dr. Patricia S. Schwartz

98P-0504

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WASHINGTON, DC 20510-3704

OFFICIAL BUSINESS

  
U.S.

Dockets Management Branch (HFA-305)  
Docket # 98P-0504  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

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